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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,479	10/04/2005	Pieter De Haan	O-2002.737 US	8459

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ORGANON USA, INC.
PATENT DEPARTMENT
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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,479	DE HAAN ET AL.	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *6,8 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-10 are included in the prosecution.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 3/18/05 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement.

See attached copy of PTO-1449.

Specification

4. The disclosure is objected to because of the following informalities: the word "aqueous" is misspelled as "aquous" on line 9, Page 4.

Appropriate correction is required.

Claim Objections

5. Claims 6, 8 and 9 are objected to because of the following informalities: the dosage range of gepirone HCl is "20-85ma" and should be "20-85mg". The quantity of gepirone HCl is disclosed in mg (Page 5, Table 1). Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Egberink et al. (WO 02/45753) in view of Schor et al. (US 4,369,172).

The claimed invention is a packaged tablet with a matrix consisting of at least 55% of a cellulose ether. The tablet has a water activity of at most 0.6 and is packaged to delay moisture uptake.

Egberink teaches a pharmaceutical formulation comprising gepirone hydrochloride, a cellulosic polymer and microcrystalline cellulose (Page 1, lines 4-7). The amount of cellulosic polymer is from 70 to 85 wt% and the amount of gepirone hydrochloride is from 13 to 21 wt% (Page 1, line 35 to Page 2, line 1). HPMC is the preferred cellulosic polymer (Page 2, lines 25-27). Example 1 discloses tablet compositions with gepirone HCl dosages ranging from 40mg to 80mg and HPMC levels ranging from 70 to 75% (Page 4, lines 15-19). The compressed tablets are stored in tight containers until further use or testing (Page 5, line 29).

Egberink does not expressly teach the water activity of the tablet.

Schor teaches a carrier base material consisting of hydroxypropylmethylcellulose (HPMC) (Col. 1, lines 12-14). This carrier base has "greater stability, greater hardness, lower friability, reduced water solubility ... from hydroxypropylmethylcellulose" (Col. 2,

lines 49-53). Example 1 discloses tablets with lithium carbonate and 57% of HPMC (400mg per 702mg tablet). The tablets "had a moisture content of 4.5-5.5%" (Col. 4, lines 19-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a tablet with HPMC (as a cellulose ether) at 70 to 85 wt%, as suggested by Egberink, combine it with the tablet containing 57% of HPMC and with a moisture content of 4.5-5.5%, as taught by Schor, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because both the references teach tablet formulations with HPMC levels greater than 55% and with a low moisture level in the tablet and the advantages of a tablet with low moisture content include greater stability, greater hardness and lower friability (Schor, Col. 2, lines 49-51).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 1, the limitation of a packaged tablet and the limitation of delaying moisture uptake would have been obvious over the tablets that are stored in tight containers, as taught by Egberink (Page 5, line 29). One skilled in the art would optimize the stability of the tablets by protecting them from moisture and would use blister packs, foil packs, bottles, desiccants, and other packaging materials used in the

art to prevent moisture uptake by contents. The limitation of at least 55% of a cellulose ether would have been obvious over the HPMC levels of 57% taught by Schor (Col. 4, lines 19-51) and HPMC levels ranging from 70 to 75% in the example taught by Egberink (Page 4, lines 15-19). The limitation of the tablet water activity would have been obvious over the low moisture content of the tablets taught by Schor (Col. 4, lines 50-51).

Regarding instant claim 2, the limitation of the water activity of the tablet of less than 0.55 would have been obvious over the tablet containing 57% of HPMC and having a moisture content of 4.5-5.5%, as taught by Schor (Col. 4, lines 19-51).

Regarding instant claim 3, the limitation of a packaged tablet and the limitation of delaying moisture uptake would have been obvious over the tablets that are stored in tight containers, as taught by Egberink (Page 5, line 29). The limitation of at least 55% of a cellulose ether would have been obvious over the HPMC levels of 57% taught by Schor (Col. 4, lines 19-51) and HPMC levels ranging from 70 to 75% in the example taught by Egberink (Page 4, lines 15-19). The limitation of the water content of the tablet less than 9% w/w would have been obvious over the low moisture content of the tablets taught by Schor (Col. 4, lines 50-51).

Regarding instant claims 4 and 7, the limitation of more than 65% of a cellulose ether would have been obvious over the 70 to 85 wt% of cellulosic polymer (HPMC levels ranging from 70 to 75% in Example 1) as taught by Egberink (Page 1, line 35 to Page 2, line 1 and Page 4, lines 15-19).

Regarding instant claims 5 and 10, the limitation of hydroxypropyl methylcellulose as the cellulose ether would have been obvious over the HPMC taught by Egberink (Page 2, lines 25-27) and Schor (Col. 1, lines 12-14).

Regarding instant claims 6 and 8, the limitation of 20-85mg of gepirone HCl would have been obvious over the gepirone HCl dosages (ranging from 40mg to 80mg) taught by Egberink (Page 4, lines 15-19). Egberink also teaches that the treatment regime starts with about 20mg of gepirone HCl per day and is gradually built up to 60-100mg of gepirone HCl per day (Page 2, lines 7-11). One skilled in the art would modify the quantity of the active ingredient gepirone HCl based on the desired dosage during the process of routine experimentation.

Regarding instant claim 9, the limitation of the tablet comprising 20-85mg of gepirone HCl would have been obvious over the gepirone HCl dosages (starting from 20mg and building up to 100mg) taught by Egberink (Page 4, lines 15-19 and Page 2, lines 7-11). The limitation of the tablet matrix consisting of more than 65% of a cellulose ether would have been obvious over the 70 to 85 wt% of cellulosic polymer (HPMC levels ranging from 70 to 75% in Example 1) as taught by Egberink (Page 1, line 35 to Page 2, line 1 and Page 4, lines 15-19).

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-

9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SUPERVISORY PATENT EXAMINER
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